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6449 7550 OSTRIED, TRIG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			EXAMINER	
			SHIN, DANA H	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Application No. Applicant(s) 10/520 470 TUSCHL ET AL. Office Action Summary Examiner Art Unit DANA SHIN 1635 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 15 December 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 45-92 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 45-92 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (FTO/SB/08)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 15, 2009 has been entered.

Status of Claims

Claims 1, 3-8, 11-16, 20, 22-36, and 38-44 that were previously examined have been cancelled. Applicant has added new claims, claims 45-92. Accordingly, claims 45-92 are pending and under examination on the merits in the instant case.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-8, 11-16, 20, 22-36, and 38-44 filed with the RCE have been fully considered but are moot in view of the claim cancellation and the new grounds of rejections. See below.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1635

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 recites the limitation "wherein the single-stranded RNA molecule" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. For examination purpose, the limitation will be interpreted to mean "wherein the single-stranded siRNA molecule", and the same interpretation will be applied to all dependent claims.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-92 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at 1563-64, 19 USPQ2d at

The factors to be considered when analyzing claims for compliance with the written description requirement include: A) actual reduction to practice; B) disclosure of drawings or structural chemical formulas; C) sufficient relevant identifying characteristics (e.g., complete structure, partial structure, physical and/or chemical properties, structure/function correlation); D) method of making the claimed invention; E) level of skill and knowledge in the art; and F) predictability in the art.

The claims are drawn to a single-stranded siRNA molecule-mediated, RISC-activated target nucleic acid cleavage method in an animal cell or a plant cell in vitro or in vivo. With regard to the claimed "single-stranded siRNA molecule", the claims recite minimal structural requirements such that it is either "14 to 50 nucleotides in length" or "15 to 29 nucleotides in length" and is "complementary" to target molecule but can also have "at least one mismatch", "at least one modified nucleoside" such as "2'-sugar modification" and "at least one phosphorothioate linkage".

As for the factor pertaining to "actual reduction to practice", the specification describes that the inventors performed an experiment for RISC-activated target cleavage with a single-stranded antisense siRNA or 20-25 nucleotides in length (100 nM) in HeLa S100 extract. The specification also explicitly teaches that the inventors "were *unable* to detect RISC activity from antisense siRNA" in *Drosophila* embryo lysates (emphasis added). See page 35. In addition, the specification teaches that non-phospholyated single-stranded, lamin A/C-specific antisense siRNA (200 nM) reduced lamin A/C by 25% in HeLa cells, whereas "5' phosphorylated siRNAs reduced the lamin A/C content to less than 5%". See page 36, which is also supported by the factor "disclosure of drawings" as evidenced by Figure 8B. The specification also merely reports that gene silencing occurs with phosphorylated or non-phosphorylated antisense siRNAs of 19-

Art Unit: 1635

29 nucleotides, without specifying the cell type. See page 36. Taken together, at best, the specification shows that the inventors actually practiced target cleavage method in HeLa S100 extract or HeLa cells with a single-stranded (phosphorylated or non-phosphorylated), chemically unmodified antisense siRNA of 19-29 nucleotides. In addition, the specification makes it clear that single-stranded siRNA does not mediate RISC-activated target cleavage in *Drosophila* cells.

As for the factor pertaining to "disclosure of drawings", Figure 11 sufficiently demonstrates that a single-stranded (phosphorylated or non-phosphorylated) antisense siRNA of 13-17 nucleotides in length does not inhibit lamin A/C target inhibition compared to control (GL2 ds). Further, there is no demonstration of target cleavage activity for a single-stranded siRNA that is longer than 30 nucleotides in length, nor is there a Figure showing that a chemically modified single-stranded siRNA mediates target cleavage in any given type of cell.

As for the factor "structure/function correlation", as detailed above, the specification is completely silent about whether a chemically modified structure of single-stranded siRNA or longer than 30 nucleotides in length or shorter than 15 nucleotides in length is capable of mediating target cleavage in an RISC-activated manner. Even better, the specification shows negative structure/function correlation for the single-stranded siRNAs shorter than 19 nucleotides in length (for phosphorylated) or 17 nucleotides in length (for non-phosphorylated) and for the single-stranded siRNA in *Drosophila* cells. Consistent with the disclosure of the instant application, it was also known in the art that single-stranded antisense siRNAs shorter than 19 nucleotides rarely induce RNAi in cells of *C. elegans*. See Figure 1E of Tijsterman et al. (*Science*, 2002, 295:694-697, citation of record). See also page 696: "We found that 15- and 18-nt asRNAs were ineffective". As such, it is questionable how a single-stranded siRNA molecule wherein only "14 5'-terminal nucleotides of the single-stranded RNA molecule are

Page 6

Art Unit: 1635

complementary to the nucleic acid target molecule" (see claim 47 or claim 70) can possibly mediate target cleavage. In addition, chemical modifications such as morpholino modifications incorporated into single-stranded siRNAs were known to prevent RNAi activity of the singlestranded siRNAs. See pages 695-696 including Figure 1B of Tijsterman et al. (Science, 2002). Furthermore, in addition to the lack of actual demonstration that a single-stranded, chemically modified siRNA molecule mediates target cleavage and RISC activation in any given cell in the instant specification, it was largely unknown in the art as of the filing date sought in the instant application whether a single-stranded siRNA molecule is capable of activating RISC and target cleavage in a cell when the siRNA molecule is chemically modified in any position of the nucleotide with any type of chemical modification. Even better, it was later found that an siRNA having an antisense strand that is chemically modified (e.g., 2'-deoxy, 2'-O-methyl, or phosphorothioate linkage) or an siRNA having mismatched nucleotides is ineffective in mediating target cleavage/inhibition in cells or abolishes/significantly reduces the RNAi activity. It was also later suggested that chemical modifications/mismatches in the antisense strand of an siRNA interferes with the RISC incorporation and activation. See Chiu et al. (Molecular Cell, September, 2002, 10:549-561), Hamada et al. (Antisense and Nucleic Acid Drug Development, October, 2002, 12:301-309), and Chiu et al. (RNA, 2003, 9:1034-1048). Even much better, Martinez et al. (Cell, 2002, 110:563-574, applicant's citation), consistent with the aforementioned references, taught that modifications at the 5' end of the antisense strand of an siRNA inhibits RISC activity. Note that the co-authors of the Martinez et al. reference are the coinventors of the present application. Taken together, the structure/function correlation for chemically modified, antisense siRNA molecules was largely unknown and thus unpredictable as of the earliest filing date sought in the instant application.

In addition to the lack of appropriate structure/function correlation between the breadth of the claimed siRNA structure and the target cleavage function, the specification is completely silent about a single-stranded siRNA molecule that has only partial sequence complementarity. For example, claim 47 explicitly recites that only 14 nucleotides out of a total of 50 nucleotides need to be complementary to the target sequence, thereby rendering an siRNA molecule having a 28% sequence complementarity. Similarly, claim 70 explicitly recites that only 14 nucleotides out of a total of 29 nucleotides need to be complementary to the target sequence, thereby rendering an siRNA molecule having a 48% sequence complementarity. Note that applicant has explicitly stated on the record that the claimed single-stranded siRNA does not read on a hairpinforming siRNA and that such hairpin-forming, precursor-like siRNA structure is excluded from the claimed single-stranded siRNA. See pages 11-12 of the reply filed on December 15, 2009. As such, the only possible interpretation for the structure of the partially complementary siRNA molecule claimed in claim 47 and claim 70 is that the non-hairpin forming siRNA molecule is only 28% or 48% complementary in sequence to the target molecule. As applicant must be aware, the instant specification only shows perfectly complementary "antisense" siRNA molecules. Further, examiner is not aware of any prior art of record that teaches that one can cleave target molecule in any given cell in vitro and in vivo with an siRNA molecule having a 28% sequence complementarity or activate RISC in any given cell in vitro and in vivo with an siRNA molecule having a 48% sequence complementarity. Again, applicant's attention is directed to the state of the art as of the earliest filing date sought in the instant application such that siRNAs with mismatched nucleotides (not single-stranded, but double-stranded siRNAs) were known to be ineffective in inducing RNAi activity in cells. See Chiu et al. (Molecular Cell, September, 2002, 10:549-561), wherein Chiu et al. explicitly taught that "A single mismatch

between a target mRNA and its guide strand siRNA completely *prevents target RNA cleavage* in *Drosophila* embryo lysates." by citing a 2001 Elbashir et al. reference, which was co-authored by the three named co-inventors of this application (emphasis added). See page 552, right column. That is, it was known in the art, prior to the filing date, that even a single mismatch between the "guide" strand (same as antisense strand) of an siRNA molecule and a target molecule "prevents" target cleavage in a cell. As such, given the significant impact of a single mismatched nucleotide on siRNA target cleavage activity, a person of ordinary skill in the art would have highly doubted target cleavage activity or RISC activation of a single-stranded siRNA having only 28% or 48% sequence complementarity (thus having more than a single mismatched nucleotide between the antisense strand sequence and the target sequence), thereby suggesting the unpredictability of the structure/function correlation for the minimally complementary single-stranded siRNAs explicitly used in claims 47 and 70 and embraced by the rest of the claims pending in the instant case.

As for the factor "level of skill and knowledge in the art", the prosecution record (see the declaration filed on October 7, 2008) indicates that a single-stranded siRNA mediated RNAi in mammalian cells was unpredictable and unknown at the time the invention was made. For example, the declarant expressly stated under Section 1001 of Title 18 of the United States Code that "based on the literature available at the priority date of the present application, the skilled person would have concluded that it would have been hopeless to use short single-stranded RNA molecules for RNAi in mammalian systems" (emphasis added). See paragraph 5. As such, as of the earliest filing date sought in the instant application, it is reasonably concluded that using a single-stranded antisense siRNA in a mammalian cell to cleave target RNA and activate RISC was known to be impossible as of the earliest filing date sought in the instant application.

In view of the foregoing, the "predictability in the art" as of the earliest filing date sought in the instant application would have been relatively low pertaining to the claimed methods embracing a single-stranded siRNA-mediated target inhibition in any mammalian cell including "a human cell" (see claims 68 and 91) in vitro and in vivo as broadly written in the instant case.

Note that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." (emphasis added). See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)("[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated."). See also MPEP §2163.

In the instant case, as stated hereinabove, the specification merely shows inhibition methods with chemically unmodified single-stranded RNA that is longer than 17-19 nucleotides in length in a cultured mammalian cell *in vitro*, and furthermore, the variability of target inhibition effects depending on the size of the RNA and the type of cells was explicitly disclosed in the instant specification as well as by Tijsterman et al. (*Science*, 2002, 295:694-697, citation of record) and by the declaration filed on October 7, 2008. Hence, the limited teaching disclosed

in the specification does not provide a sufficient variety of species (a representative number of

species) to reflect the variation within the claimed genus.

Hence, in view of the totality of the factors considered hereinabove, further in light of the reasons stated above, it is concluded that the instant specification does not clearly allow persons of ordinary skill in the art to recognize that the inventors invented the genus claimed in the instant case because it is clear that applicant was not in possession of the claimed genus as of the filling date sought in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 45-47, 49-50, 63, 65-66, and 92 are rejected under 35 U.S.C. 102(a) as being anticipated by Tijsterman et al. (*Science*, 2002, 295:694-697, citation of record).

This rejection is directed to a very limited claim embodiment drawn to a method of cleaving a target nucleic acid in a cell of a *C. elegans* animal and progeny embryos thereof with a single-stranded antisense siRNA molecule that is perfectly complementary to the target nucleic acid sequence; is from 19-40 nucleotides in length; and comprises a phosphate analog at the 5' terminus.

Tijsterman et al. teach a method of cleaving target pos-I mRNA with a single-stranded antisense siRNA of 25 nucleotides in length in C. elevans, wherein the siRNA contains a 5'

Art Unit: 1635

phosphate group. See the entire reference including Figure 1A and Note number 8. They teach that single-stranded siRNAs up to 40 nucleotides in length are effective in triggering gene silencing. See page 696. Accordingly, all claim limitations are taught by Tijsterman et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 44-47, 49-50, 63-64, 69-70, 72-73, 86-87, and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamilton et al. (*Science*, 1999, 286:950-952) in view of Vaucheret et al. (*Journal of Cell Science*, 2001, 114:3083-3091) and Tijsterman et al. (*Science*, 2002, 295:694-697, citation of record).

Note that this rejection is directed to a very limited claim embodiment drawn to a method of cleaving a target nucleic acid in a cell of a plant cell with a single-stranded antisense siRNA

Art Unit: 1635

molecule that is perfectly complementary to the target nucleic acid sequence; is from 19-40 nucleotides in length; and comprises a phosphate analog at the 5' terminus.

Hamilton et al. suggest that a single-stranded antisense RNA of 25 nucleotides in length participates in posttranscriptional gene silencing (PTGS) in a plant cell. They do not teach that the 25-mer single-stranded antisense RNA in the plant cell cleaves and activates RISC, nor do they teach that the RNA comprises a 5'-triphosphate.

Vaucheret et al. teach that PTGS in plants "results in the specific degradation of a population of homologous RNAs" and "shows similarities to RNA interference", thereby activating RISC-like complex. See page 3083, left column and the summary; Figure 2.

Tijsterman et al. teach that one can cleave target mRNA in a cell with a 5'phosphorylated, single-stranded siRNA of 25 nucleotides in length. See the entire reference
including Figure 1A and Note number 8.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use make a 5'-phosphorylated single-stranded antisense RNA of 25 nucleotides in length and introduce it to a plant cell.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success so as to degrade/cleave target mRNA in the plant cell, because the post-transcriptional gene silencing role of single-stranded antisense RNAs of 25 nucleotides in length in plants was suggested in the art as taught by Hamilton et al., and because the mechanistic similarities (e.g., RISC-like involvement, target mRNA degradation) between RNAi and PTGS were suggested in the art as taught by Vaucheret et al. Further, since 5'-phosphorylated single-stranded RNAs of 25 nucleotides in length were demonstrated to cleave target mRNA via RNAi in a cell as taught by Tijsterman et al., one of ordinary skill in the art would have had a

reasonable expectation of success in making and using a 5'-phosphorylated single-stranded RNA of 25 nucleotides in length to degrade target mRNA and active RISC in a plant cell. Accordingly, the claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-92 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-19, 23-25, and 36-37 of copending Application No. 11/880,355. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the reference claims are drawn to an RNAi method with an siRNA of 21-23 nucleotides in length that mediates RNAi in a cell. Although the reference claims do not recite a "single-stranded" siRNA, the specification of 11/880,355 teaches that the siRNA used in the claimed methods can be "single-stranded RNA". See page 2. As such, the scope of the instant claims and that of the reference claims overlap with each other, and thus, the instant claims and the reference claims are not patentably distinct from each other.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tracy Vivlemore (Acting SPE) can be reached on 571-272-2914. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin Examiner Art Unit 1635

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